IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

GILEAD SCIENCES, INC. and EMORY UNIVERSITY,

Plaintiffs,

v.

MYLAN INC. and MYLAN PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE KAULL'S ORDER/OPINION DENYING MOTION TO COMPEL RELEVANT DISCOVERY

Pursuant to Federal Rule of Civil Procedure 72(a), Plaintiffs Gilead Sciences, Inc. and Emory University object to the Order/Opinion of Magistrate Judge Kaull dated July 1, 2015, denying Plaintiffs' motion to compel production of documents directly relevant to Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.'s (collectively, "Mylan") newly-articulated nonenablement defense. Dkt. No. 190 (Ex. A).

With respect, Judge Kaull's Order/Opinion was premised on a fundamental misunderstanding of relevant patent law. Relying on a single Federal Circuit opinion, Judge Kaull denied Plaintiffs' motion on the grounds that "an invalidity defense looks no further than the four corners of initial patent and patent application." Order/Opinion at 3 (citing *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) (Ex. B)). But a review of the page from the *Streck* opinion cited in the Order/Opinion reveals that, at that point, the Federal Circuit was discussing the *written description* defense (which may in fact be focused

on, if not strictly limited to, "the four corners of the specification"), *not* the separate defense of *nonenablement* (which is most assuredly not so limited). Indeed, several pages after the lone page cited in the Opinion/Order, the *Streck* opinion specifically addresses "Enablement," and correctly summarizes that defense as an intensely factual inquiry:

> The enablement requirement is met where one skilled in the art, having read the specification, could practice the invention without "undue experimentation." *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988) . . . . Whether undue experimentation is required "is not a single, simple factual determination, *but rather is a conclusion reached by weighing many factual considerations.*" *ALZA*, 603 F.3d at 940 (citing *Wands*, 858 F.2d at 737).

Streck, 665 F.3d at 1288 (emphasis added).

Under the appropriate legal standard applicable to the nonenablement defense that Mylan is *actually* asserting in this matter (rather than the legal standard applicable to a written description defense that it is not asserting), there can be no reasonable dispute that Plaintiffs' motion to compel the production of documents directly relevant to the factual issue of "undue experimentation" should be granted. Pursuant to Rule 72(a), therefore, the Court should set aside the Order/Opinion denying Plaintiffs' motion as clearly erroneous and contrary to law.

A. Procedural Background

On May 28, 2015, Plaintiffs filed their Motion to Compel (Dkt. No. 160). *See* Plaintiffs' Reply in Support of Its Motion to Compel Defendants to Produce Documents at 1 (Dkt. No. 183). As of that date – the original close of fact discovery, and a mere three weeks before the extended close of fact discovery – Mylan had produced fewer than 25,000 pages of documents, comprised mostly of its ANDA and of publicly available prior art. *Id.*

Evidently recognizing that Plaintiffs' complaints regarding its document production were

legitimate, following the filing of the Motion, Mylan finally began to make a meaningful attempt to comply with its discovery obligations. Between the time that motion was filed and the date that Mylan filed its opposition brief, Mylan produced an additional 140,000 pages of responsive documents, nearly six times the volume of its pre-Motion productions. But a remaining, narrowed dispute remained: Mylan continued to withhold documents relating to ANDA No. 90-049, as well as the related PEPFAR and WHO filings, on the grounds that those documents are "not relevant." *Id.* at 1. The Order/Opinion denied Plaintiffs' Motion to Compel as to that remaining category of documents on the grounds that "everything that the Plaintiffs would need to defend against a claim of invalidity through enablement theory is within the four corners of the Plaintiffs' own patent," Order/Opinion at 4 – again citing the single page from the *Streck* opinion that addresses the *written description* defense, not the nonenablement defense actually being asserted by Mylan in this matter.

B. Argument

The requested PEPFAR/WHO documents are directly relevant to Mylan's nonenablement defense, which squarely raises the factual issue of whether the asserted patent claims require "undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The requested documents are expected to show that Mylan has been able to make multiple, different stable fixed dose combinations of FTC and TDF without undue experimentation.[1] Plaintiffs' Reply at 2-3 (Dkt. No. 183). Mylan does not dispute that its PEPFAR/WHO products were tested for stability under the precise accelerated stability conditions claimed in two of the four asserted patents. *Id.* at 3. But Mylan's refusal to produce the requested documents impairs

[1] To be clear, Mylan's work was *after* the named inventors had conceived of the claimed invention and reduced it to practice.

Plaintiffs' ability to compare the PEPFAR/WHO products to the asserted patent claims to determine whether those products fall within the scope of those claims, and deprives Plaintiffs of compelling evidence of enablement and of no "undue experimentation." *Id.*

The Order/Opinion, however, concluded that such documents were not relevant based on the proposition that Mylan's nonenablement defense "looks no further than the four corners of initial patent and patent application." Order/Opinion at 3. That is clearly erroneous. The Order/Opinion based that conclusion on a Federal Circuit opinion analyzing the distinct invalidity defense of written description, which has no relevance to this litigation.

The requested documents, however, are reasonably likely to be highly relevant to Mylan's actual defense of nonenablement, which "is a conclusion reached by weighing many factual considerations." *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (citing *Wands*, 858 F.2d at 737). In fact, the seminal enablement opinion from the Federal Circuit, *In re Wands*, lists eight factors a court should consider when determining whether a patent's disclosure requires "undue experimentation," and is thus nonenabling. The very first of those factors articulates precisely why the requested documents are indeed relevant to Mylan's defense: "the quantity of experimentation necessary." *Wands*, 858 F.2d at 737. Stated simply, if the requested documents demonstrate that Mylan's PEPFAR/WHO products fall within the scope of the asserted claims, such documents likely would disprove Mylan's nonenablement/"undue experimentation" defense.[2] Indeed, that is presumably precisely why

[2] Courts routinely find evidence that others are able to practice the claims of the invention without undue experimentation relevant to "[t]he extent of the enabling disclosure." *See, e.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 162-63 (D. Mass. 2001) ("The fact that these [third party] researchers were capable of making EPO-producing cells using non-human transcription control sequences and either amplified or non-amplified EPO DNA in various types of cultured cells including human cells further suggests that Amgen's specification was enabling."), *aff'd in part*, 314 F.3d 1313 (Fed. Cir. 2003); *see also Bruning v. Hirose*, 161 F.3d 681, 686 (Fed. Cir. 1998) (affirming reliance on testing done by the plaintiff's expert during an interference to show

Mylan is fighting not to produce these documents.

The Order/Opinion also based its denial on the fact that Plaintiffs had not filed their Motion to Compel within 30 days of Mylan's original objection to certain requests that would cover the PEPFAR/WHO documents (although Mylan did not object to other requests that would likewise cover those documents), but that conclusion was inextricably intertwined with the Order/Opinion's erroneous conclusion that the documents were not relevant because "an invalidity defense looks no further than the four corners of initial patent and patent application."

The Order/Opinion wrongly concluded that, because Mylan first pled "invalidity" under 35 U.S.C. § 112 as a defense in its Answer, Defenses and Counterclaims filed on August 12, 2014, Gilead was "on notice" as to that defense. Order/Opinion at 4. Mylan's pleading, however, did not even specify which of the multiple defenses available under section 112 it was relying on, let alone its specific arguments. Based on Mylan's Answer, Plaintiffs *could not* have been on notice of Mylan's specific "nonenablement" arguments, and therefore could not have determined the potential relevance of the PEPFAR/WHO documents at that time.

As Plaintiffs' Reply details, Plaintiffs in fact could not have been aware of the potential relevance of the PEPFAR/WHO documents until Mylan fully articulated its nonenablement/undue experimentation defense – which it did not do until June 18, 2015, the very last day of fact discovery and a mere *eight days* before Plaintiffs filed their Reply specifically seeking the production of those documents. Plaintiffs' Reply at 2, 4-5 (Dkt. No. 183). Mylan does not explain, and the Order/Opinion does not address, how Plaintiffs were to anticipate the specific nonenablement/undue experimentation defense that Mylan *itself* did not

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that one skilled in the art could practice the invention without undue experimentation).

articulate until June 18, 2015. The 30 day time limit of Local Rule 37.02(b) thus provides no legitimate basis to deny Plaintiffs' timely motion to compel. At the very least, the Court should grant an exception to that time limit here, given that Plaintiffs' failure to file the specific motion earlier was directly due to the (in)action of the non-moving party, which failed to set forth its nonenablement defense in detail until June 18, 2015.

C. Conclusion

For all of these reasons, the Court should set aside the Order/Opinion of July 1, 2015, and grant Plaintiffs' Motion to Compel and order Mylan to produce all non-privileged, responsive documents in its possession, custody, or control responsive to Request Nos. 21, 22, 23, 37, 40, 58, 60-62, and 73, including but not limited to documents concerning Mylan's ANDA No. 90-049, Mylan's PEPFAR and WHO products, and documents concerning Mylan's development of fixed dose combinations of FTC and TDF other than those subject to ANDA No. 20-6436, and including the removal of all non-privileged redactions from its already produced documents relating to such products. The Court should further order that Plaintiffs may continue the 30(b)(6) deposition of Mylan as to any newly produced information and/or questions that its 30(b)(6) witness could not answer based on Mylan's withholding of relevant discovery.

Dated: July 14, 2015

Respectfully submitted,

/s/ Chad L. Taylor

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on July 14, 2015, a true copy of the foregoing **PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE KAULL'S ORDER/OPINION DENYING MOTION TO COMPEL RELEVANT DISCOVERY** was served upon counsel of record for Defendants via the Court's CM/ECF system, which will send notification of the filing to the counsel of record for Defendants.

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